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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/646,271

08/22/2003

Jay D. Caplan

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EXAMINER

ROZANSKI, MICHAEL T

ART UNIT

PAPER NUMBER

3768

MAIL DATE

DELIVERY MODE

08/04/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/646,271

Applicant(s)

CAPLAN ET AL.

Examiner

MICHAEL ROZANSKI

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period **will** apply and **will** expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply **will**, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 May 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 and 29-72 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-27 and 29-72 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/21/08 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6, 8-9, 11, 13, 15-27, 29-33, 35-37, 39, 41, and 43-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over ***Auer et al*** (US 5,383,467) in view of ***Narciso, Jr.*** (US 5,217,456).

Auer et al disclose an optical catheter 15, and the use of an interferometer for analysis (col. 1, lines 6-11). At the distal end 27 of catheter 15, a coil is formed that has an outer diameter of 0.014 inches and a lens 58 are present, and could function as fins of the main catheter body (col. 5, lines 27-49). The catheter is positioned within a blood

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vessel 26, which is illuminated by a light source capable of operating at several wavelength simultaneously (col. 5, lines 9-14), wherein a beam of reflected energy is returned from tissue mass 28 by operation of catheter and fiber coupler 18 (col. 4, lines 41-43). Signal data from the photodetector 31 and signal detector 24 provides input to the computer 21, which includes a display output 35 whereat the X-Y plane configuration of vessel 26 is displayed and a determination of when the probe is close enough to vessel wall may be made (col. 4, lines 41-61). The amplitude of the interference signal is plotted as the Y coordinate, wherein a threshold could be set at a specific amplitude, and as a variable function of the X position of the catheter's distal end 27 within the vessel (col. 4, lines 41-61). The spikes in the signal plot represent discontinuities in the tissue mass 28 and the average slope of the signal plot between adjacent spikes represent the average extinction coefficient for the tissue mass (col. 4, lines 62-68). Thus, Auer et al disclose determining a mechanical relationship between the probe and the vessel walls, wherein the distance relationship provides an assessment of the vessel walls.

However, Auer et al do not disclose triggering an assessment of the vessel walls when a mechanical relationship has been determined or initiating diagnosis or treatment of the vessel walls in response to analyzing the optical signals indicative of a spectral response if the probe is determined to be close enough to the vessel walls to enable the diagnosis or treatment. In the same field of endeavor, Narciso, Jr. teach of an intravascular optical radial imaging system where scattered light interacts with tissue and various wavelengths of fluorescence light return to the catheter. The return signal

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enters a spectral analyzer where it is separated into various wavelengths, which indicate the composition of the vessel (col.I 2, lines 37-68). The spectral analyzer is used to determine where plaque is present in a blood vessel, which also indicates a narrowing of the vessel. Thus, Narciso, Jr. teaches receiving optical signals from vessel walls through intervening blood, analyzing the signals to determine whether plaque (and subsequently whether the vessel is narrowing and the probe is closer to the vessel wall, and using the signals to diagnose the vessel walls as healthy or unhealthy.

Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to have incorporated the teachings of Narciso, Jr. in order to alleviate the problem of not knowing the probe position in relation to the vessel wall while improving diagnosis or treatment of vessel wall.

Claims 65-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Kohno et al** (US 5,647,359) in view of **Narciso, Jr.** (US 5,217,456).

Kohno et al disclose a catheter probe 11 with LEDs 17 and 18 for emitting optical signals and a photodiode for detecting the signals (col 4, lines 10-15). The measured reflected light intensity vary depending on blood flow pulsation, respiration, and also on movement of the distal end portion of the catheter 11. Movement of the catheter results in reflection by the blood vessel wall. In many instances, the reflected light intensity increases due to the influence of the vessel wall. Kohno et al use a threshold value in order to identify minimum values of the measured signals (col 6, lines 15-29).

Therefore, there is a comparison between the spectral content of the optical signals to a

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spectral response of blood (i.e. the minimum values). In other words, the spectral characteristics of vessel walls and intervening fluid are each unique due to absorption, scattering, and fluorescence, wherein the vessel wall gives a reflected signal with higher intensity. A relationship is formed wherein the higher the reflected light intensity signal, the closer the distal end of the probe is to the blood vessel wall. However, Kohno et al is primarily concerned with the reflected signal from the blood, as opposed to the vessel walls.

Narciso, Jr. teach of an intravascular optical radial imaging system where scattered light interacts with tissue and various wavelengths of fluorescence light return to the catheter. The return signal enters a spectral analyzer where it is separated into various wavelengths, which indicate the composition of the vessel (col.I 2, lines 37-68). The spectral analyzer is used to determine where plaque is present in a blood vessel, which also indicates a narrowing of the vessel. Thus, Narciso, Jr. teaches receiving optical signals from vessel walls through intervening blood, analyzing the signals to determine whether plaque (and subsequently whether the vessel is narrowing and the probe is closer to the vessel wall, and using the signals to diagnose the vessel walls as healthy or unhealthy. It would have been obvious to modify comparison of spectral responses of Kohno et al, to provide an assessment or diagnosis of the vessel walls as taught by Narciso, Jr, because the differences spectral content between vessel walls and intervening fluid is known and such would be useful in determining the presence of plaque.

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Claims 7, 10, 12, 14, 34, 38, 40, and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Auer et al** (US 5,383,467) and **Narciso, Jr.** (US 5,217,456) as applied to claims 1, 9, 11, 26, 37, and 39 in view of **Kohno et al.**

Auer et al and Narciso, Jr substantially disclose all features of the current invention as set forth above but do not describe comparing the spectral content of the optical signals to a spectral response of intervening fluid. However, Kohno et al teach of comparing spectral content, which is indicative of how close the probe tip is to the vessel walls. It would have been obvious to the skilled artisan to modify Auer/Narciso, Jr, as taught by Kohno et al, because such would allow for a diagnosis using the reflected optical signals.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-27 and 29-64 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-73 of copending Application No. 10/426,750 in view of Auer et al (US 5,383,467).

Copending Application '750 claims features of the current invention including a method for analyzing blood vessels in the presence of intervening fluid comprising irradiating vessel walls with an optical source, collecting spectral responses, determining spectral responses of the vessel walls from the collected responses, and generating information for the assessment of vessel walls (i.e. diagnosis) in response to the determined spectral response of vessel walls. The spectral response of blood samples may be taken from the patient and may, subsequently, be compared to known spectral features of blood. Furthermore, the method includes analysis of the signal comprising algebraic analysis and chemometric analysis. '750 do not claim using optical signals to determine the mechanical relationship between the probe and the vessel. In the same field of endeavor, Auer et al teach of a determination of such a mechanical relationship (col. 4, lines 41-61). It would have been obvious to one with ordinary skill in the art at the time the invention was made to incorporate this teaching in order to alleviate the problem of not knowing the probe position in relation to the vessel wall.

This is a provisional obviousness-type double patenting rejection.

Response to Arguments

Applicant's arguments with respect to claims 65-72 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's arguments filed 5/21/08 have been fully considered but they are not persuasive. Applicant argues that Narciso, Jr does not teach determining or assessing probe head-blood vessel wall distance using the optical signals or trigger analysis based on such distance. However, Narciso uses a spectral analyzer to determine where plaque is present. This comprises assessing the blood vessel walls and also gives an indication of the probe head distance to the vessel wall because the blood vessel is narrower when plaque is present. In addition, the presence of plaque triggers analysis based on the distance, wherein a higher amount of plaque signifies a diagnosis of the walls as less healthy.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL ROZANSKI whose telephone number is (571)272-1648. The examiner can normally be reached on Monday - Friday, 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric F Winakur/
Primary Examiner, Art Unit 3768

MR